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## DETAILED ACTION

## Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly

claiming the subject matter which the applicant regards as his invention.

2. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Claim 31 recited "a surgeon's knot" which is indefinite for one

to know the boundary of the claim limitation.

## Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

 Claims 1-5, 7-17 and 29-33 rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,709,694 to Greenberg et al. (Greenberg).

In Reference to Claim 1:

Greenberg teaches:

A laparoscopic needle delivery device, comprising a generally elongate member (72, Fig. 3), the member having a needle carrying portion (68a, 68b, Fig.

5) for releasably carrying a needle (110, Fig. 6) and a loop carrying portion (74,

Fig. 7) for releasably carrying at least one loop of filamentary material (86, Fig.

11), said loop carrying portion (74, Fig. 7) being constructed and arranged to

enable said at least one loop (Figs. 12-14) to be released from the elongate

member whilst still formed as a loop.

In Reference to Claim 2:

Greenberg teaches:

A device as claimed in claim 1 (see rejection of Claim 1 above), wherein

the filamentary material is suture material (86, Fig 8) and has a more proximal

portion and a more distal portion, said elongate member has a hollow central

lumen (66 Fig. 8) to receive said more proximal portion of said suture material,

and said at least one loop is formed in said more distal portion of said suture

material (Fig. 14).

In Reference to Claim 3:

Greenberg teaches:

A device as claimed in claim 2 (see rejection of Claim 2 above), wherein

the more distal portion of said suture material extends out of the central lumen at

the distal tip of the elongate member (fig. 8).

In Reference to Claim 4:

Greenberg teaches:

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A device as claimed in claim 1 (see rejection of Claim 1 above), wherein the needle carrying portion (68a, 68b, Fig. 6) of the elongate member (72, Fig. 3) has a longitudinal axis and the needle carrying portion (68a, 68b, Fig. 6) is constructed and arranged to allow the needle (110, Fig. 10) to be carried in an orientation in which the needle is generally aligned with that longitudinal axis

In Reference to Claim 5:

(Fig. 10).

Greenberg teaches:

A device as claimed in claim 1 (see rejection of Claim 1 above), wherein the needle carrying portion (68a, 68b, Fig. 6) comprises one or more pre-formed apertures provided in a wall of the elongate member.

In Reference to Claim 7:

Greenberg teaches:

A device as claimed in claim 1 (see rejection of Claim 1 above), wherein the loop carrying portion (74, Fig. 7) is provided to one side of the elongate member (72, Fig. 3) so that said at least one loop (Fig. 14) is wholly positioned to that side of the elongate member (72, Fig. 3).

In Reference to Claim 8:

Greenberg teaches:

A device as claimed in claim 1 (see rejection of Claim 1 above), wherein the loop carrying portion (74, Fig. 7) is arranged to carry said at least one loop (Figs. 12-14) alongside the elongate member (72, Fig. 3).

In Reference to Claim 9:

Greenberg teaches:

A device as claimed in claim 1 (see rejection of Claim 1 above), wherein the elongate member (72, Fig. 3) has a longitudinal axis and the loop carrying portion (74, Fig. 7) is arranged to carry said at least one loop adjacent to said axis (Figs. 2-14).

In Reference to Claim 10:

Greenberg teaches:

A device as claimed in claim 9 (see rejection of Claim 9 above), wherein said carried at least one loop is not coaxial to said longitudinal axis (Figs. 12-14).

In Reference to Claim 11:

Greenberg teaches:

A device as claimed in claim 1 (see rejection of Claim 1 above), wherein said loop carrying portion (74, Fig. 7) comprises a projection under which said at least one loop can be carried to be carried by said elongate member (72, Figs. 12-14).

In Reference to Claim 12:

Greenberg teaches:

A combination of: a device as claimed in claim 1 (see rejection of Claim 1 above); said needle (110, Fig. 14); and a length of said filamentary material (86,

Fig. 14).

In Reference to Claim 13:

Greenberg teaches:

A combination as claimed in claim 12 (see rejection of Claim 12 above), wherein the needle (110, Fig. 14) is attached to the distal end of the length of filamentary material (86, Fig. 14), the length of filamentary material has said at least one loop formed therein (Fig. 14) at a position spaced from said distal end, said at least one loop is engaged with said loop carrying portion (74, Fig. 12) so as to be carried thereby and said needle (110, Fig. 12) is engaged with said

needle carrying portion so as to be carried thereby.

In Reference to Claim 14:

Greenberg teaches:

A method of using the combination of claim 13 (see rejection of Claim 13 above) to form a suture (86, Fig. 14), the method comprising releasing the needle (110, Fig. 14) from the needle delivery device (68a, 68b, Fig. 6), passing the

needle through the elements (T, Fig. 8) to be sutured, passing the needle through the centre of said at least one loop (Fig. 14) and tensioning said at least one loop to cause said loop to contract to form a knot (Col. 6, lines 29-30) in the filamentary material.

In Reference to Claim 15:

Greenberg teaches:

A method as claimed in claim 14 (see rejection of Claim 14 above), wherein said at least one loop is removed from the loop carrying portion before the needle is passed through the loop's Centre (Fig. 13).

In Reference to Claim 16:

Greenberg teaches:

A method as claimed in claim 14 (see rejection of Claim 14 above), wherein said at least one loop is being carried by the loop carrying portion (74, Fig. 10) when the needle is passed through the loop's centre.

In Reference to Claim 17:

Greenberg teaches:

A method as claimed in claim 1 (see rejection of Claim 1 above), wherein the elements to be sutured are intracorporeal (Col. 6, lines 49-50).

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In Reference to Claim 29:

Greenberg teaches:

A device as claimed in claim 1 (see rejection of Claim 1 above), wherein said at least one loop of filamentary material comprises part of a plurality of adjacent loops-formed in said filamentary material (Figs. 12-14).

In Reference to Claim 30:

A device as claimed in claim 29 (see rejection of Claim 29 above), wherein said plurality of adjacent loops form the basic structure of a clove hitch knot (Figs. 12-14).

In Reference to Claim 31:

A device as claimed in claim 29 (see rejection of Claim 29 above), wherein said plurality of adjacent loops form the basic structure of a surgeon's knot (Fig. 14).

In Reference to Claim 32:

A device as claimed in claim 1 (see rejection of Claim 1 above), wherein said plurality of loops are constructed and arranged so that, when the loops are tensioned, they will contract to form at least one knot in the filamentary material (Figs. 12-14, Col. 6, lines 25-34).

In Reference to Claim 33:

A device as claimed in claim 32 (see rejection of Claim 32 above), wherein said plurality of loops are constructed and arranged so that, when the loops are tensioned, they will contract to form a double knot (Figs. 12-14).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Greenberg in view of US Patent No. 5,490,858 to Shuter (Shuter).

In Reference to Claim 6:

Greenberg in view of Shuter teach:

A device as claimed in claim 1 (see rejection of Claim1 above),

Greenberg fails to teach:

Wherein the needle carrying portion of the elongate member includes

material which can be penetrated by a needle, enabling the needle to be inserted

into said material so as to create a hole in said material thereby to be carried by

the elongate member.

Shuter teaches:

Wherein the needle carrying portion of the elongate member includes

material (41, Fig. 11) which can be penetrated by a needle (Figs. 10-11),

enabling the needle to be inserted into said material so as to create a hole in said

material thereby to be carried by the elongate member.

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It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the needle carrying portion (39, Fig. 11) on a device (arms 40, 42, Fig. 11) of Shuter with the device of Greenberg for the use of needle retaining means.

## Conclusion

- 5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patent No. 5,364,409 to Kuwabara et al. teaches an endoscopic needle holder.
- Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809.
  The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

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